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09/125,114	08/18/1998	IAN ASHLEY PRICE	P8129-8004	7439

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/125,114	PRICE, IAN ASHLEY	
	Examiner	Art Unit	
	Shaojia A Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-15,20-25,32-37 and 39-53* is/are pending in the application.

4a) Of the above claim(s) *11-15,20-25,32-37 and 48-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-47,52 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 6, 2004 has been entered.

This Office Action is a response to Applicant's request for continued examination (RCE) filed February 6, 2004, and amendment and response to the Final Office Action (mailed September 8, 2003), filed February 6, 2004 wherein claims 1-10, 16-19, 26-31 and 38 are cancelled, and claims 39-53 are newly submitted.

Currently, claims 11-15, 20-25, 32-37 and 39-53 are pending in this application.

It is noted that Claims 11-15, 20-25 and 32-37 are withdrawn from further consideration pursuant to 37 CFR 1 .142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse recorded in the previous Office Action October 18, 2002.

Note that new claims 48-51 drawn to a method of obtaining an onset-hastened analgesic and/or anti-pyretic response comprising the oral administration of a non-effervescent compressed solid dosage herein are seen to be independent and distinct from the originally elected invention as discussed in the previous Office Action October 18, 2002. Therefore, claims 48-51 are withdrawn from further consideration pursuant to

37 CFR 1 .142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 39-47 and 52-53 are examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-47 and 53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment with respect to new claims 39-47 and 53 has been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for the negative limitation, "the ibuprofen medicament does not contain a calcium salt of ibuprofen in combination with an alkali metal salt of ibuprofen" (emphasis added). The original specification discloses that "Preferably, the medicament is in the form of racemic or S(+)-ibuprofen. Representative examples include alkaline earth metal salts, for example the sodium or potassium salts of ibuprofen; alkaline earth metal salts, eg the **calcium** or magnesium salts of ibuprofen" (emphasis added, see page 7 lines 14-17 of the specification). Thus, calcium salt of ibuprofen is one of preferred salts disclosed as the instant invention.

Any negative limitation or exclusionary proviso must have basis in the original disclosure. See Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), aff 'd mem., 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. See MPEP § 2163 - § 2163.07(b) for a discussion of the written description requirement of 35 U.S.C. 112, first paragraph.

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 39-47 and 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armitage et al. (WO 9220334, PTO-892) in view of Gregory et al. (5,262,179 of record).

Armitage et al. disclose a pharmaceutical composition comprising ibuprofen salt in racemic mixture of S-ibuprofen, such as alkaline earth metal salts, for example the

sodium salt of ibuprofen (see page 1 lines 8-22, page 2 lines 1-5), and a carrier, a compressible filler component such as lactose, microcrystalline, and calcium phosphate (see page 5 lines 33 to page 6), combined with a disintegrating component such as maize starch and lubricating agents (see page 5 lines 4-15). Armitage et al. also disclose the effective amounts of ingredients therein, such as preferably, a solid composition comprises a) 10-99% of ibuprofen or a doses for example 100 mg, 200mg, 400mg, or 800mg of ibuprofen; b) 1-90% of a filler or diluent, c) 0.1-10% of a lubricating agent (disintegrating component) and other ingredients, see page 5 lines 1-3 and 27-32.

The cited prior art does not expressly disclose the employment of the particular sodium carbonate or sodium bicarbonate 3-20% by weight in the ibuprofen dosage of Armitage et al. and the particular amount sodium salt of ibuprofen may be 40-60%.

Gregory et al. discloses that ibuprofen salts have an unpleasant taste and, therefore, it is advantageous to provide a dosage form that masks the taste of ibuprofen by incorporating an alkali metal bicarbonate into the dosage form (see abstract), especially sodium bicarbonate, e.g., in 10% or 26.9% by weight, and ibuprofen in 15.5% 16%, 19.7% or 20% by weight, and the various weight ratio of sodium bicarbonate to ibuprofen is also disclosed (see col.2 lines 27-30, the particular compositions comprising the instant ingredients with specific amounts within the instant claimed, see Example 1-20 of col.4-10), For the sodium salt of ibuprofen, see col. 3, lines 26-30.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular sodium carbonate or sodium bicarbonate in

3-20% by weight in the ibuprofen dosage of Armitage et al. and to optimize the amount of sodium salt of ibuprofen may be 40-60% in the compositions of the prior art cited.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular sodium carbonate or sodium bicarbonate 3-20% by weight in the ibuprofen dosage of Armitage et al. because it is known that ibuprofen salts have an unpleasant taste and, therefore, it is advantageous to provide a dosage form that masks the taste of ibuprofen by incorporating an alkali metal bicarbonate into the dosage form especially sodium bicarbonate according to Gregory et al. The instant effective amounts or ratio of sodium bicarbonate and ibuprofen are also known according to Gregory et al.

Note that the cited prior does not disclose the inherent properties of the composition such as crushing strength, disintegration time or compression force as instantly claimed. Any properties exhibited by or benefits provided the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical or similar compositions, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product.

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 39-47 and 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geyer et al. (5,380,535, of record) in view of Gregory et al. (5,262,179 of record).

Geyer et al. discloses chewable compositions for oral delivery of unpalatable drugs (abstract). Chewable products in the form of compressed tablets (claim 10) or uncompressed powder (see column 2, lines 37-39). The composition therein comprises an unpalatable drug, a lipid and various other conventional excipients and additives. For mannitol and lactose, see column 6, lines 2-6. For microcrystalline cellulose, see column 7, lines 26-28. These are Applicants preferred compressible fillers of instant claims 8 and 31. For sodium bicarbonate, see column 6, lines 16-28. For sodium starch glycolate, croscarmellose sodium and cross-linked polyvinylpyrrolidone (crospovidone), the disintegrating components of instant claims 9 and 30, see column 6, lines 42-68.

A compressed tablet also comprising lubricants and flow aids is disclosed at Column 7, lines 20-30. An ibuprofen composition comprising 0.5-40 wt.% ibuprofen, 25-75 wt. % granulating agent (mannitol and lactose compressible fillers), 1-30 wt.%

dispersal agent (sodium starch glycolate and croscarmellose sodium) and 0.5-7 wt.% lubricant is disclosed at column 8, lines 1-36. US 535 0.2-10 wt.% of inert diluents such as flavorants and sweeteners (col. 8, lines 20-30). See also Examples 3 and 5 and claims 3 and 17 for ibuprofen, sodium bicarbonate, compressed tablets and mannitol.

US '535 discloses a powder that can be compressed into a tablet comprising ibuprofen, a compressible filler, a disintegrant, sodium bicarbonate, lubricants and flow aids.

US '535 does not disclose the crushing strength, disintegration time or compression force as instantly claimed, a salt of ibuprofen or a solid formulation having a layer as instantly claimed and the cited prior art does not expressly disclose the employment of the particular sodium carbonate or sodium bicarbonate in 3-20% by weight in the ibuprofen dosage of Geyer et al. and the particular amount sodium salt of ibuprofen may be 40-60%.

Gregory et al. discloses that ibuprofen salts have an unpleasant taste and, therefore, it is advantageous to provide a dosage form that masks the taste of ibuprofen by incorporating an alkali metal bicarbonate into the dosage form (see abstract), especially sodium bicarbonate, e.g., in 10% or 26.9% by weight, and ibuprofen in 15.5% 16%, 19.7% or 20% by weight, and the various weight ratio of sodium bicarbonate to ibuprofen is also disclosed (see col.2 lines 27-30, the particular compositions comprising the instant ingredients with specific amounts within the instant claimed at Example 1-20 of col.4-10), For the sodium salt of ibuprofen, see col 3, lines 26-30.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular sodium carbonate or sodium bicarbonate in the amount herein and 3-20% by weight in the ibuprofen dosage of Geyer et al. and to optimize the amount of sodium salt of ibuprofen may be 40-60% in the compositions of the prior art cited.

One of ordinary skill in the art would expect a composition containing the same components to exhibit similar properties. Additionally, it is considered within the skill in the art to select optimal parameters in order to obtain beneficial effects. The recitation of the compression force leads the claim to a product-by-process claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The prior ad teaches dosage forms containing the same components as instantly claimed. Therefore, absent evidence of unexpected results, the crushing strength, disintegration time and compression force are not considered critical to the invention.

Further, one having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular sodium carbonate or sodium bicarbonate 3-20% by weight in the ibuprofen dosage of Geyer et al. because it is known that ibuprofen salts have an unpleasant taste and, therefore, it is advantageous

to provide a dosage form that masks the taste of ibuprofen by incorporating an alkali metal bicarbonate into the dosage form especially sodium bicarbonate according to Gregory et al. The instant effective amounts or ratio of sodium bicarbonate and ibuprofen are also known according to Gregory et al. Thus, a *prima facie* case of obviousness exists.

Applicant's arguments filed on February 6, 2004 with respect to the rejections made under 35 U.S.C. 103(a) in the previous Office Action September 8, 2003 have been considered but are moot in view of the new ground(s) of rejection above.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is 571.272.0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on 571.272.0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
May 11, 2004